

COOPERATIVE AGREEMENT

Institutional Review Board Agreement
for Protection of Human Subjects
BY and BETWEEN
Fred Hutchinson Cancer Research Center (FHCRC)
Seattle, Washington
and
Washington State Department of Social and Health Services (DSHS)
and
Washington State Department of Health (DOH)
Olympia, Washington

The DSHS IRB is the primary designated institutional review board for the Washington State Department of Health. The FHCRC, and DSHS and DOH, share a mutual concern for safeguarding the rights and welfare of human subjects involved in research activities conducted under the direct and indirect sponsorship of the respective parties. Each party has a policy and procedures that are in compliance with the federal regulations on the protection of human subjects.

In order to establish mutually beneficial human subjects review procedures, this Agreement is entered into by the above named parties as of the date below.

- A. This Agreement is applicable only where the work involves access to individually identifiable records for utilization of such records in research (as defined in 45 CFR 46 and RCW 70.54.250) when said records are contained in the Washington State Cancer Registry (WSCR) established by DOH pursuant to RCW 70.54.230 and in which FHCRC participates under contract with DOH.
- B. Human subjects review conducted by either party shall be acceptable to the other party; provided that each investigator shall have the opportunity to submit any protocol, which is subject to this agreement and which has been denied approval by either IRB, to an appeal IRB consisting of three representatives from DOH, three representatives from FHCRC and one unaffiliated member selected and confirmed unanimously by all six DOH/FHCRC members. All decisions made by the appeal IRB shall be final and binding.
- C. It is further agreed that the party performing IRB review will provide the non-reviewing party a copy of each approved IRB application, and an excerpt of the minutes relevant to such application and/or review.
- D. Designation of the IRB with primary review responsibility shall be based upon the origin of the identifiable WSCR data and the affiliation of the research investigators, in accordance with the Summary of IRB Review Responsibility incorporated into this Agreement as Attachment A. For the purposes of this Agreement, affiliation with the FHCRC or the DOH does not extend to FHCRC-affiliated or DOH-affiliated students at institutions of higher education who perform some or all of their research activities for educational purposes. Operating procedures specified in Attachment A have been developed by the participating IRB officials in cooperation with appropriate institutional officials, and may be modified as circumstances require by the mutual agreement of the aforementioned parties.

- E. Any modifications or changes to this Agreement must be approved in writing by both parties and amended to this Agreement.
- F. This Agreement will be continuous, but may be terminated by either party upon submission of written notice 90 days in advance of the effective termination date.

AUTHORIZED INSTITUTIONAL OFFICIALS

Signature: Karen Hansen

Date: 5/10/02

Name: Karen Hansen
Title: Human Protections Administrator
Institution: Fred Hutchinson Cancer Research Center
(FWA00001920)
Address: 1100 Fairview Ave. N.
D5-100, P.O. Box 19024
Seattle, WA 98109-1024
Telephone: 206 667-4867

Signature: Michael Garrick

Date: 4/30/2002

Name: Michael Garrick
Title: Human Protections Administrator
Institution: Department of Social and Health Services
(FWA00000326)
Address: 1115 Washington Street SE
P.O. Box 45205
Olympia, WA 98504-5205
Telephone: 360 902-8075

Signature: Juliet VanEenwyk

Date: 5-2-02

Name: Juliet VanEenwyk
Title: State Epidemiologist for
Non-Infectious Conditions
Institution: Department of Health
(FWA00000327)
Address: 1102 SE Quince
P.O. Box 47812
Olympia, WA 98504-7812
Telephone: 360 236-4250

SUMMARY OF IRB REVIEW RESPONSIBILITY
RESEARCH INVOLVING USE OF
WASHINGTON STATE CANCER REGISTRY RECORDS¹

	13-County Data ²	Outside 13-County Data	Statewide Data
FHCRC Affiliated Investigators ³	FHCRC IRB	FHCRC IRB with DOH-Affiliated Ad Hoc Member	FHCRC IRB with DOH-Affiliated Ad Hoc Member
DOH Affiliated Investigators ³	DOH IRB with FHCRC-Affiliated Ad Hoc Member	DOH IRB	DOH IRB with FHCRC-Affiliated Ad Hoc Member
Investigators Not Affiliated with FHCRC or DOH ³	FHCRC IRB	DOH IRB	DOH IRB with FHCRC-Affiliated Ad Hoc Member

¹ For research in which the use of WSCR records does not include contacts with human subjects, and which qualifies for expedited review, both IRB's waive the requirement for ad hoc members to be involved in the review.

² FHCRC has a contract with SEER (NO1-CN-05230) which involves data collection in 13 contiguous counties in northwest Washington State. The 13 counties are: Clallam, Grays Harbor, Island, Jefferson, King, Kitsap, Mason, Pierce, San Juan, Skagit, Snohomish, Thurston, Whatcom.

³ Students at institutions of higher education may have an affiliation with FHCRC or DOH for purposes that may or may not be related to their educational program. For purposes of this Agreement, research conducted by FHCRC-affiliated or DOH-affiliated students in which some or all of the research activity is performed for educational purposes (e.g., thesis or dissertation projects, class projects, independent study projects, etc.), shall be reviewed as if the investigator is not affiliated with either the FHCRC or DOH.